IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Marvin J. Slepian

Serial No.: 10/072,766 Art Unit: 1636

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For: *ENDOMURAL THERAPY*

Commissioner for Patents
P.O. Box 1450
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AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed on July 26, 2004, please consider the following remarks. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

Amendment

1. (original) A method of treatment comprising locally penetrating and entering the body of an organ, organ component or tissue structure with minimal damage to obtain access to endomural zones of an organ.

2. (original) The method of claim 1 further comprising depositing in the midzone therapeutic agents and systems.

3. (currently amended) The method of claim 2 wherein the therapeutic agents are selected from the group consisting of drugs, cells and polymers and diagnostic ~~and/or~~ or therapeutic devices.

4. (currently amended) The method of claim 3 wherein the polymers ~~may be~~ are degradable or non degradable.

5. (currently amended) The method of claim 3 wherein the polymers are selected from the group consisting of solid matrices, porous matrices, hydrogels, organogels, colloidal ~~syspensions~~ suspensions, microparticles and microcapsules, ~~anoparticles~~ nanoparticles and combinations ~~therof~~ thereof.

6. (currently amended) The method of claim 3 wherein the drugs are selected from the group consisting of anti-infectives, antibiotics, antifungal, antihelminthic, antiparasistic agents, anticancer agents, anti-proliferative agents, anti-migratory agents, anti-inflammatory agents, metalloproteases, proteases, ~~thromblytic~~ thrombolytic agents, fibrinolytic agents, steroids, hormones, vitamins, ~~charbohydrates~~ carbohydrates, lipids proteins, peptides and enzymes.

7. (original) The method of claim 3 wherein the drugs are proliferative growth factors selected from the group consisting of PDGF, FGF, TGF, EDGF,

Epidermal GF, NGF, ILGF, Hepatocyte scatter factor, angiogenic growth factors, serum factors, collagen, laminin, tenascin, SPARC, thrombospondin, fibronectin, vimentin and other matrix factors.

8. (currently amended) The method of claim 3 wherein the cells are ~~selected from the group consisting of~~ autogenous similar cells ~~(i.e. mesenchymal for mesenchymal)~~ from adjacent normal zones of the same or different organs.

9. (currently amended) The method of claim 3 wherein the cells are ~~selected from the group consisting of~~ autogenous differing cells ~~(i.e. mesenchymal for ectodermal or splenocytes for endothelial cells)~~ from adjacent normal zones of the same or different organs.

10. (currently amended) The method of claim 3 wherein the cells are therapeutic factors produced by or in the form of stem cells or other ~~progeneitor~~ progenitor cells.

11. (currently amended) The method of claim 3 wherein the cells are explanted and ~~clonally or otherwise~~ expanded *in vitro* for implantation~~, either without genetic modification or genetically modified, before implantation~~.

12. (currently amended) The method of claim 3 wherein the therapeutic factors are selected from the group consisting of genes, plasmids, episomes, viruses, and viroids~~, or other microorganisms for therapeutic or synthetic purpose~~.

13. (currently amended) The method of claim 3 wherein the therapeutic factors are selected from the group consisting of heat shock proteins, ~~or~~ stress response proteins, and ~~or~~ inducers of heat shock or stress response proteins.

14. (currently amended) The method of claim 1 further comprising forming a ~~where~~ a cavity, ~~or~~ containment space or reservoir area ~~does not exist~~ in the endomural ~~zone, creating such a space for therapeutic placement~~ and depositing therapeutic agents and systems in the cavity, containment space or reservoir.

15. (currently amended) A device comprising a hollow tubular member with an end penetrating or ~~cuting~~ cutting means causing minimal collateral damage and means for delivery of therapeutic agents into endomural tissue.

16. (original) The device of claim 15 wherein the member is rigid made of metal, polymer, or composite.

17. (original) The device of claim 15 wherein the member is flexible and comprises a catheter-like device.

18. (original) The device of claim 15 wherein the member is attached to a single or multiple reservoirs for therapeutic agent containment and delivery.

19. (original) The device of claim 15 wherein the member has an expansile cutter at the distal end to create a tissue space.

20. (original) The device of claim 15 further comprising diagnostic or therapeutic sensors.

21. (original) The device of claim 15 further comprising projectile means to ballistically transfer particles through the ectoluminal or endoluminal zone for retention in the endomural zone.

22. (original) The device of claim 21 wherein the projectile means is selected from the group comprising mechanical acceleration, electrical transfer, spark explosion, and gas explosion.

23. (currently amended) The device of claim 15 further comprising means for indirect or direct guidance ~~means~~.

24. (currently amended) The device of claim 23 wherein the means for direct guidance is selected from the group consisting of fiber optic imaging systems, endoscopes, direct tip cameras, CCD, C-MOS or other chip or electrical video systems, and ultrasound or GPS positioning systems.

25. (currently amended) A kit comprising ~~The~~

a device ~~of claim 15 in a kit~~ comprising a hollow tubular member with an end penetrating or cutting means causing minimal collateral damage and means for delivery of therapeutic agents into endomural tissue and

a void filling material or implant ~~which contains electroactive agents~~.

26. (currently amended) The ~~device~~ kit of claim ~~15~~ 25 ~~comprising a~~ wherein the void filling material or implant ~~which~~ can locally sense, store or telemeter physical, chemical or biological information.

27. (currently amended) The ~~device~~ kit of claim ~~15~~ 25 comprising ~~electoactive~~ electroactive or electroconductive polymers which may be directly or externally activated via transcutaneous energy delivery to elicit positive or negative galvanotaxis ~~(tissue healing or cell movement to or from based on local persistent or intermittent electrical current).~~

28. (currently amended) The ~~device~~ kit of claim ~~15~~ 25 further comprising a therapeutic for induction of angiogenesis or myogenesis.

29. (currently amended) The ~~device~~ kit of claim 28 ~~comprising a~~ wherein the therapeutic is selected from the group of angiogenic growth factors, inflammatory

angiogenic polymers or polymer constructs, ~~electoactive~~ and electroactive or other microinjurious or locally stimulatory polymers.

30. (currently amended) The ~~device~~ kit of claim 28 ~~comprising~~ wherein the therapeutic comprises cells selected from the group consisting of endothelial cells, EC bone marrow precursor cells, other stems cells smooth muscle cells or precursors, combinations, neural cells or neural stem cells or combinations thereof ~~with above are placed~~.

31. (currently amended) The device of claim 15, wherein the device is suitable for nerve regeneration.

32. (currently amended) The ~~device~~ kit of claim ~~15~~ 25 comprising a bioactive polymer.

33. (currently amended) The ~~device~~ kit of claim ~~15~~ 25 further comprising stress response inducing agents or ~~actual~~ stress response proteins.